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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,104	04/28/2005	Yong Kwee	053466-0401	5920

22428 7590 04/06/2010

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EXAMINER	
SANG, HONG	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
04/06/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,104	KWEE ET AL.	
	Examiner	Art Unit	
	HONG SANG	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,12 and 23-32* is/are pending in the application.

4a) Of the above claim(s) *24 and 26-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,12,23,25 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RE: Kwee et al.

1. Applicant's response filed on 2/23/2010 is acknowledged. Claims 1, 12, and 23-32 are pending. Claims 2-11, and 13-22 have been cancelled. Claims 24 and 26-31 have been withdrawn from consideration as being drawn to non-elected inventions. Claims 1 and 32 have been amended.

2. Claims 1, 12, 23, 25 and 32 are under examination.

Rejections Withdrawn

3. The rejection of claims 1, 12, and 25 under 35 U.S.C. 103(a) as being unpatentable over Treon et al. (Semin. Oncol. 2000, 27(5): 598-613, IDS) in view of Ohtomo et al. (Biochem. Biophy. Res. Commun., 1999, 258:583-591, IDS), and Chiriva-Internati et al. (Cancer Gene Therapy, 2001, Dec., 8(Suppl 2): S27) is withdrawn in view of applicant's amendment to the claims.

Rejections Maintained

Claim Rejections - 35 USC § 103

4. The rejection of claims 1, 12, 23, and 25 under 35 U.S.C. 103(a) as being unpatentable over Treon et al. (Semin. Oncol. 2000, 27(5): 598-613, IDS) in view of Ohtomo et al. (Biochem. Biophy. Res. Commun., 1999, 258:583-591, IDS), and Chiriva-Internati et al. (Cancer Gene Therapy, 2001, Dec., 8(Suppl 2): S27), further in view of

WO 200177362 (Pub. Date: 10/18/2001, IDS), as evidence by Porgador et al. (J. Exp. Med., 1995, 182: 255-260, IDS) is maintained.

The response states that the Chiriva reference describes that "improvement in T-cell priming by DC, giving continuous protein expression, as most proteins have short half-lives.", and thus Chiriva-Internati destroys the motivation for pulsing a soluble HM1.24 protein/peptide into dendritic cells. Treon describes treatment of plasma tumor cells, such as multiple myeloma, by immunotherapy using dendritic cells pulsed with whole tumor antigen, nuked DNA or whole tumor RNA... The description suggest the use of full length cancer antigen, tumor RNA but it does not suggest use of a part of a cancer antigen, tumor RNA, etc. WO 2001/77362 describes only that a soluble HM1.24 protein can be used for immunoassay and does not suggest the use of a soluble HM1.24 peptide for immunotherapy using a T cell response. Accordingly, a person of ordinary skill in the art reading the above mentioned cited references, may consider that a vaccine comprising dendritic cells pulsed with a partial peptide rather than a full length peptide is not effective, and may also not have been motivated to construct a vaccine by pulsing a partial (soluble) HM1.24 peptide.

Applicant's arguments have been carefully considered but are not persuasive.

MPEP 2144 [R-6] states "The rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). See also *In re Eli Lilly & Co.*, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990) (discussion of reliance on legal precedent); *In re Nilssen*, 851 F.2d 1401, 1403, 7 USPQ2d 1500, 1502 (Fed. Cir. 1988) (references do not have to explicitly suggest combining teachings); *Ex parte Clapp*, 227 USPQ 972 (Bd. Pat. App. & Inter. 1985) (examiner must present

convincing line of reasoning supporting rejection); and *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993) (reliance on logic and sound scientific reasoning)".

Chiriva-Internati et al. teach that pulsing dendritic cells via an adeno-associated viral vector/HM1.24 recombinant generates rapid, significant cytotoxic T lymphocytes and interferon activity against multiple myeloma and synthetic HM1.24-positive autologous targets (see abstract). Therefore, Chiriva-Internati et al. have demonstrated that HM1.24 antigen expressed by the viral vector and presented by the dendritic cells are capable of inducing significant cytotoxic T cell response. While Chiriva-Internati et al. do not teach pulsing dendritic cells directly with HM1.24 antigen, the state of the prior art is that dendritic cells can be pulsed (loaded) with various agents including whole tumor antigen, naked DNA or whole tumor RNA (see page 604, left column of Treon et al.), peptides from a tumor antigen (see Porgador). As a further evidence, Boccaccio (US 7,252,996B2, Date of Patent 8/7/2007, PCT Pub. Date: 7/18/2002) discloses "Cells may be antigen loaded by phagocytosis, pinocytosis, affinity binding, fusion, nucleic acid (DNA, RNA) transfer or receptor mediated uptake, according to methods known by a man skilled in the art. The dendritic cells culture medium may be completed with soluble or particulate antigens, including tumor target cells, cell debris, or specific peptides against which an immune response is expected (see column 4, lines30-51)". In view of the state of the art and the teachings of Chiriva-Internati that HM1.24 antigen is capable of inducing significant cytotoxic T cell response, it would have been obvious to one skilled in the art to either pulse dendritic cells via an adeno-associated viral vector/HM1.24 recombinant, or pulse dendritic cells with HM1.24 antigen or peptides

thereof. Applicant's arguments of teaching away are not persuasive. "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). Finally, one skilled in the art would have been motivated to use the HM1.24 antigen disclosed in WO200177362 for making the dendritic cell vaccines because the HM1.24 antigens of WO200177362 are recombinant proteins that can be made in a large amount with high efficiency and high purity. For these reasons, the rejection is deemed proper and is therefore maintained.

5. The rejection of claims 1, 12, 23, 25 and 32 under 35 U.S.C. 103(a) as being unpatentable over Treon et al. (Semin. Oncol. 2000, 27(5): 598-613, IDS) in view of Ohtomo et al. (Biochem. Biophy. Res. Commun., 1999, 258:583-591, IDS), Chiriva-Internati et al. (Cancer Gene Therapy, 2001, Dec., 8 (Suppl 2): S27), WO 200177362 (Pub. Date: 10/18/2001, IDS), as evidenced by Porgador et al. (J. Exp. Med., 1995, 182: 255-260, IDS)), and further in view of Thurner et al. (J. Exp. Med., 1999, 190(11): 1669-1678, IDS) is maintained.

Applicants presented the same arguments as for the prior 103(a) rejection, these arguments are not persuasive for the same reasons set forth above (see paragraph 4).

Conclusion

6. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG SANG whose telephone number is (571)272-8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hong Sang/
Examiner, Art Unit 1643

/Larry R. Helms/

Supervisory Patent Examiner, Art Unit 1643